

prescribed significantly higher number of drugs compared to those without diabetes and age ≤ 50 years. The top three prescribed medication groups were antianemic preparations (B03), minerals (A12) and vitamins (A11). Vitamin D analogues were prescribed to 31.3% of the patients. The predominantly prescribed vitamin D analogue was calcitriol. Around 91% of the patients were prescribed phosphate binders (PB). Calcium carbonate (88.8%) was the most commonly prescribed phosphate binder, whereas sevelamer and lanthanum were seldom prescribed. None of the patients was prescribed calcium acetate and aluminum-based PB. **CONCLUSIONS:** Patients with CKD stage 5D are prescribed higher number and variety of drugs for the management of comorbidities associated with kidney disease. Although non-calcium/non-aluminum based PB have less side effects as compared to calcium-based PB, they are seldom prescribed.

PUK6

PREVALENCE OF CHRONIC KIDNEY DISEASE IN INDIA: A SYSTEMATIC REVIEW AND META-ANALYSIS OF OBSERVATIONAL STUDIES

Ahlawat R¹, Tiwari P¹, D'Cruz S², Singhal R³

¹National Institute of Pharmaceutical Education and Research (NIPER), S.A.S. Nagar (Mohali), Punjab, India, ²Government Medical College & Hospital, Chandigarh, India, ³Independent Health and Outcome Researcher, S.A.S. Nagar (Mohali), Punjab, India

OBJECTIVES: Chronic kidney disease (CKD) is one of the most commonly occurring non-communicable diseases in India. CKD is associated with significant morbidity, mortality and economic burden in India. The objective of the present study is to estimate the prevalence of CKD in India. **METHODS:** A systemic search of published literature was carried out using PubMed, Elsevier ScienceDirect, Cochrane library databases and Google scholar (from 1990 to April 2015) by two independent reviewers. Reference list of the related articles was also screened to find out the relevant studies. CKD definition of KDIGO guideline was used for inclusion criteria. Cochrane Q-statistics test and I² statistics were used to assess the heterogeneity. Random effect model was used. Comprehensive Meta-Analysis software (Version 2.2, Biostat, Englewood NJ) was used. **RESULTS:** Five studies were selected as per inclusion criteria. These studies covered the different geographical regions in India. The numbers of participants ranged from 2091 to 5588. Pooled rate estimates suggest that 56.11% (95% CI, 48.46–63.75) of the patients were male. Hypertension and diabetes were found to be the most common comorbidities according to overall pooled estimates [48.67 (95% CI, 19.30–78.05) and 17.39 (95% CI, 6.67–28.12), respectively]. Modification of Diet in Renal Disease (MDRD) formula for GFR calculation was used by all studies. According to MDRD, CKD pooled prevalence in people over 18 years was found to be 2.97% (95% confidence interval [CI], 1.38%–4.56%). However, Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula was used by two studies and pooled prevalence found to be 3.51%. Overall prevalence of end stage renal disease (ESRD) was 0.27% (95% CI, 0.06%–0.48%). Pooled estimate for the prevalence of protein urea was 6.98% (95% CI, 2.04%–11.91%). **CONCLUSIONS:** The prevalence of CKD, according to MDRD and CKD-EPI was 3% and 4%, respectively. Hypertension was found to be most commonly occurring co-morbidity (49%). About 7% of the Indian patients were found to have proteinuria.

URINARY/KIDNEY DISORDERS – Cost Studies

PUK7

INTRODUCTION OF MIRABEGRON IN THE CZECH REPUBLIC FROM PAYER'S PERSPECTIVE – 1 YEAR OVERVIEW

Hudakova J, Sterba J

General Health Insurance Company of the Czech Republic, Prague 3, Czech Republic

OBJECTIVES: Our goal was to analyze the rising utilization and to provide a comparison between expected number of patients and expenditures described in the submitted budget impact analysis and the real expenditures of mirabegron for treatment of overactive bladder since its introduction in the Czech Republic in January 2014. **METHODS:** The data source for our analysis was the business activity monitoring database of the General Health Insurance Company of the Czech Republic (VZP CR). VZP CR covers approximately 60 % of marketshare in the Czech Republic. Patient was defined as an insured person with a recorded prescription for mirabegron (G04BD12) during the observed period 01-12/2014. We identified the number of patients treated with mirabegron in the observed period and determined the real expenditures. We compared the real data with submitted BIA predictions. **RESULTS:** Since the introduction of mirabegron in January 2014 its utilization rose to 1.870 million DDD till 12/2014. There were 11 437 patients treated with mirabegron and the real expenditures of VZP CR representing 60% were €2.6 million (1EUR=27,24CZK) in 2014, which strongly differed from the predicted number of patients (2026) and expenditures (€672t-€1.mil) presented in the base case budget impact analysis in the reimbursement decision published by State Institute of Drug Control (SUKL). **CONCLUSIONS:** There was a significant difference between expenditures predicted in the submitted budget impact analysis and real expenditures. The real expenditures were almost 4 times higher than the base case predictions (2,5x higher when calculated with cost per patient estimation by SUKL) and more than 30% higher than the upper predictions for the first year. Expenditures in the first quarter 2015 (€1,5 million) have already reached the predictions for the whole 2015 according to the base case. Further analysis will follow to confirm this trend.

PUK8

ECONOMIC BURDEN OF ADPKD FROM THE SPANISH HEALTH SYSTEM AND PATIENT'S PERSPECTIVE: ADVANTAGES OF DELAYING DIALYSIS

Parramon M¹, Peces R², Peces C³, Selgas R²

¹Osituka Pharmaceutical, Barcelona, Spain, ²Hospital Universitario La Paz, Madrid, Spain,

³SESCAM, Toledo, Spain

OBJECTIVES: Autosomal Dominant Polycystic Kidney Disease (ADPKD) imposes a significant economic burden on healthcare systems, particularly in advanced stages (5 or End Stage Renal Disease, ESRD). The aim of this model is to study the usual

cost of each stage of kidney disease according scheduled visits in each condition, and, therefore, to calculate the economic burden of one year dialysis for the Spanish Health System, to check the advantage of a treatment that could delay the disease progression of ADPKD. **METHODS:** The model was based in normal practice of a specific hospital, selected for its expertise within ADPKD. To build the model the following figures were provided: Hospital costs (number of expected healthcare provider visits, analytics, image diagnosis), and other expected costs (such ambulance transport and concomitant treatments for hypertension, hypercholesterolemia, hyperuricemia, pain, infections, and haematuria). In addition to this, costs from the patient's perspective, namely medication and transport costs were also analysed. **RESULTS:** The annual cost for dialysis patients in Hospital La Paz, and Madrid Province, in general, is 56,028 euros (43,980.00 € for Hospital costs, up to 600 € for medication, and 11,448 € for ambulance transport), while the rest of Chronic Kidney Disease stages (CKD stages 1-4) range annually between 809-1.551 € (Hospital costs and medication). Therefore, avoiding 1 year of dialysis will represent around 54,800 € savings. ADPKD patients cover additional expenses (up to 350 € for medication and 8-195 € for transport, annually). **CONCLUSIONS:** Dialysis extensively increases the economic burden of ADPKD, this is mainly seen in the healthcare system. ADPKD patients are faced with medication costs and travel expenses, as well as other incommensurables and non-calculated indirect costs. Therefore, a treatment able to delay the disease progression represents an important step towards patient wellbeing and big savings for the Health System

PUK9

DO SOCIOECONOMIC INEQUALITIES IMPACT THE SOCIAL COST OF CHRONIC KIDNEY DISEASE IN ITALY?

Bellelli S, Turchetti G

Scuola Superiore Sant'Anna, Pisa, Italy

OBJECTIVES: The cross sectional study aims to estimate the impact of socio-economic determinants, such as education and employment status, on the social cost of a patient with chronic kidney disease (CKD) stage IV and V pre-dialyses in Italy. **METHODS:** Individual socio-economic and clinical data have been collected for all adult outpatients in charge of 14 main Hospitals Centers in Tuscany Region during 7 weeks between 2012 and 2013. Direct medical costs have been estimated using tariff for laboratory test, diagnostic exams, visits and hospitalization and price for drugs. The cost of diet, patients and caregivers travel expenses, formal and informal care have been evaluated as direct non medical costs. The human capital approach has been used for estimating the loss of productivity of patients and caregivers. The incremental effects of socio-economic determinants on social cost of CKD were estimated by multivariate Generalized Linear Models (log link, Gamma family) adjusting for gender, age and stage of disease. **RESULTS:** No qualification and low levels of educations and non-working status characterized, respectively, the 54% and 89% of 484 patients enrolled. The raw estimated mean annual social costs were €9,855 (± €6,826) per patient with CKD. Direct medical costs amounted to €4,352 (± €4,071), representing the 44% of the overall cost, while direct non medical costs and indirect costs accounted for 30% and 26% (€2,912 ± €3,823 and €2,590 ± €3,210). The incremental effect of non-working status on direct medical cost was €1.321 (95% CI: 121-2.520, p<0,05). Employment condition and high levels of education had an incremental effect on indirect costs of €2.616 (95% CI: 391-4.841, p<0,05) and €1.039 (95% CI: 135-1.943, p<0,05). **CONCLUSIONS:** Socio-economic inequalities lead to a significant increase of direct medical cost of CKD. High education and employment status of patients significantly increase the indirect cost component of CKD social cost.

PUK10

COSTS OF OVERACTIVE BLADDER SYMPTOMS TREATMENT WITH SOLIFENACIN

Avxentyeva M¹, Gerasimova K², Khachatryan GR¹, Frolov M³, Avxentyev NA⁴, Pyadushkina E¹

¹The Russian Presidential Academy of National Economy and Public Administration, Moscow, Russia, ²I.M. Sechenov First Moscow State Medical University, Moscow, Russia, ³Volograd State Medical University, Volograd, Russia, ⁴Applied economic research Institute of Russian academy of national economy and public administration, Moscow, Russia

BACKGROUND: Overactive bladder (OAB) symptoms still are not treated in Russian Federation in most cases though several medicines are available at the pharmaceutical market. Direct and indirect costs associated with treatment are important for decision makers in health care. **OBJECTIVES:** To conduct cost analysis of solifenacin for OAB symptoms vs absence of pharmacotherapy from the Russian government perspective. **METHODS:** A mathematical model was constructed to calculate direct and indirect costs associated with OAB for 1 year. Direct medical costs included OAB treatment with solifenacin when relevant, urine pads, treatment of complications and concomitant conditions (CCC) such as urinary infections, skin rash, depression and fractures. Indirect costs included productivity losses in patients of working ages. Data on incidence of CCC for solifenacin treatment and no treatment strategies was derived from clinical studies. One-way sensitivity analysis was performed. **RESULTS:** Direct medical costs are higher for solifenacin strategy vs no treatment: €567 and €483 respectively with cost difference of €84 per patient per year. But solifenacin appears to be cost saving strategy vs no treatment when total costs are taken into account: cost difference is €40 per patient per year in favor of solifenacin. Solifenacin remains cost-saving option until the cost of urinary pads decreases twice from baseline or the solifenacin efficacy becomes less for 15% from baseline. **CONCLUSIONS:** Solifenacin seems to be an acceptable option for Russian healthcare from the government perspective.

PUK11

COST-CONSEQUENCES ANALYSIS OF FESOTERODINE AT FLEXIBLE-DOSE IN THE THERAPY OF OVERACTIVE BLADDER IN ROUTINE MEDICAL PRACTICE

Peral C¹, Rejas J², Ramos J¹, Sanchez-Ballester F³, Garcia-Mediero JM⁴

¹Pfizer S.L.U., Alcobendas (Madrid), Spain, ²Pfizer, Alcobendas, Spain, ³Department of Urology, Valencia, Spain, ⁴Hospital MD Anderson, Madrid, Spain

OBJECTIVES: To carry out a cost and consequences analysis (CCA) of treating Overactive Bladder (OAB) with two flexible-dose of Fesoterodine in routine medical practice in Spain, from the perspective of the Spanish National Health System (NHS). **METHODS:** The CCA was populated with data from an observational, retrospective and multicenter study including OAB patients, both genders, aged 18+ years-old managed under routine medical practice conditions of care. OAB patients initiating flexible-dose of Fesoterodine were included in two groups according with the flexible posology prescribed: escalating from 4-to-8mg (escalating group) or initiating and maintaining 8mg (maintaining group). Consequences included a health outcomes profile from the patient perspective and the clinician judgment. Costs were estimated from healthcare resources utilization only and used year 2015 unitary prices. The patient outcomes measures included symptoms severity and specific quality-of-life by using the OAB-q questionnaire, Patient Perception Bladder Condition (PPBC), Patient Perception Urgency Scale (PPUS), and Treatment Benefit Scale (TBS). Clinician judgment was approached by the Clinical Global Impression (CGI) scale. General linear models, logistic and ordinal regression adjusting by covariates were applied. **RESULTS:** A total of 350 (156 in maintaining group and 194 in escalating) symptomatic OAB patients were extracted from the study to populate the CCA. Adjusted healthcare total costs were not statistically different; €50.6 (CI:157.4–55.1), $p=0.361$. However, patient-reported-outcomes were significantly better in the maintaining group than in the escalating; OAB-q symptoms (22.6 vs. 26.8, $p=0.015$), HRQoL (74.5 vs. 71.1, $p=0.053$), less patients with urinary incontinence (29.5% vs. 46.4%, OR= 0.4 (CI:0.3–0.7), $p=0.001$, and better perception or urgency OR= 1.8 (CI:1.2–2.8), $p=0.008$. **CONCLUSIONS:** Despite the study design, this cost-consequences analysis found that initiating 8mg dose of fesoterodine was associated with similar healthcare costs but better patient outcomes than escalating from 4mg in the treatment of Overactive Bladder in routine medical practice.

PUK12

HOSPITAL COSTS OF CONTRAST-INDUCED NEPHROPATHY

Brillet G¹, Aubry P², Schmidt A³, Catella L³, Julien L⁴, Bénard S³

¹Centre de néphrologie de Châteauroux, Châteauroux, France, ²Hôpital Bichat-Claude Bernard, Paris, France, ³st[e]jeu consultants, Oullins, France, ⁴GE Healthcare, Vélizy-Villacoublay, France

OBJECTIVES: The use of low-osmolar contrast media has reduced the frequency of Contrast-Induced Nephropathy (CIN), however, it still exists. As no data are available in France, a study was set up to estimate the hospital burden associated to this complication in terms of medical resource used and hospital costs. **METHODS:** A retrospective, observational study was conducted using the French exhaustive hospital discharge database (PMSI). Stays with an interventional radiology or cardiology procedure involving the use of a contrast media were identified in 2012 and 2013 in adults. CIN was defined as the occurrence over the stay of a nephropathy CIM-10 code or unscheduled dialysis procedure. Patients' characteristics and stays were described, as well as associated costs. **RESULTS:** In 2012 and 2013, 1,047,329 stays were identified with an interventional procedure. Patients were mainly men (68.0%) with a mean age of 66.1±13.8. Among those patients, 25.8% were diabetics, 9.2% had Chronic Kidney Disease (CKD), 3.4% were suffering from heart failure and 0.2% had a cardiogenic shock. Overall CIN rate was 3.1%. CIN resulted in an extra length of stay (LOS) of 15.8 days (20.5 vs 4.7 days, $p<0.0001$) and an extra cost of €12,413 (€15,765 vs €3,352, $p<0.0001$). This result was very similar in each subgroup analysis (extra cost of €11,030 for diabetics, €11,437 for CKD and €7,257 for patients with heart failure). In France, the hospital cost of CIN reached a total cost €401,023,050 in 2012 and 2013, making it €200,511,525 per year. **CONCLUSIONS:** This study shows that CIN was associated with significant hospital costs due to increased LOS, even more when dialysis occurred. The hospital cost of CIN could partially cut down through better preventing measures including safer media use.

PUK13

COST-EFFECTIVENESS OF A FIXED-DOSE COMBINATION OF SOLIFENACIN PLUS TAMSULOSIN OCAS FOR THE TREATMENT OF LOWER URINARY TRACT SYMPTOMS ASSOCIATED WITH BENIGN PROSTATIC HYPERPLASIA IN SPAIN

Toledo A¹, Llopis A¹, Mora A¹, Rubio-Terrés C², Rubio-Rodríguez D², Nazir J³

¹Astellas Pharma SA, Madrid, Spain, ²Health Value, Madrid, Spain, ³Astellas Pharma EMEA, Chertsey, UK

OBJECTIVES: To assess the cost-effectiveness of a fixed-dose combination (FDC) of solifenacin 6 mg/day plus an oral controlled absorption system formulation of tamsulosin (TOCAS 0.4 mg/day) compared to tolterodine ER 4 mg/day concomitantly given with tamsulosin 0.4 mg/day in men with lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH) in Spain. **METHODS:** A Markov model with a 4-week cycle period was developed for men aged ≥ 45 years with LUTS/BPH who have moderate-to-severe storage and voiding symptoms. The model estimated cost effectiveness over an analytical time horizon of 1 year from the perspective of the Spanish National Health System (NHS). Direct health care costs (drug acquisition, primary care physician visits and surgical procedures) were considered. The effectiveness of treatments was measured using quality-adjusted life-years (QALYs) gained. Utility values were derived from EQ-5D data collected in a randomized controlled trial. Other model inputs were derived from the literature or clinical expert opinion. Deterministic and probabilistic sensitivity analyses (SA) were undertaken. **RESULTS:** The FDC of solifenacin 6 mg plus TOCAS 0.4 mg was associated with a gain of 0.003 QALYs at an additional cost of €25 per patient. The resulting incremental cost effectiveness ratio (ICER) was €8,471 per QALY gained. Time horizon, discontinuation or withdrawal rates and utility values were the main drivers of cost-effectiveness. The probability of FDC solifenacin 6 mg plus TOCAS being cost-effective relative to tolterodine plus tamsulosin was 97.3% at a willingness to pay threshold of €30,000 per QALY. **CONCLUSIONS:** The FDC of solifenacin 6 mg plus TOCAS is a cost-effective treatment strategy compared with tolterodine plus tamsulosin for men with storage and voiding LUTS/BPH in the Spanish NHS.

PUK14

PROJECTED CLINICAL AND ECONOMIC IMPACT OF GRAZOPREVR (GZR, MK-5172)/ELBASVIR (EBR, MK-8742) FOR CHRONIC HCV GENOTYPE 1 INFECTION IN CHRONIC KIDNEY DISEASE

Elbasha EH¹, Ferrante S¹, Agarwal E², Greaves W¹, Nwankwo C¹

¹Merck & Co., Inc., Kenilworth, NJ, USA, ²NewAgeSys, Inc., Princeton Junction, NJ, USA

OBJECTIVES: The health and economic burden of Hepatitis C virus (HCV) infection in chronic kidney disease (CKD) patients in the United States is significant. GZR (NS3/4A protease inhibitor)/EBR (NS5A inhibitor) have been shown to be highly effective and well tolerated in HCV G1 patients with advanced CKD. Our objective was to project the clinical and economic impact of GZR/EBR compared with no treatment (NoTx) and pegylated interferon plus ribavirin (peg-IFN/RBV). **METHODS:** A state-transition model of chronic HCV, liver disease, and CKD was developed to project lifetime incidence of liver complications, including hepatocellular carcinoma (HCC), life expectancy, discounted quality-adjusted life years (QALY), and discounted disease cost (COST) (2015 US dollars). Efficacy of GZR/EBR was obtained from C-SURFER, a phase 2/3, randomized, double-blind, placebo-controlled trial of GZR/EBR in HCV G1 patients in CKD stages 4/5. In the pre-specified primary population, the proportion of patients achieving sustained viral response 12 weeks after the completion of therapy was 0.99 (0.95–1.00). Based on the results of a meta-analysis, we assumed an efficacy of 0.60 (0.47–0.71) for peg-IFN/RBV. Data on baseline characteristics of the simulated patients were obtained from NHANES. Natural history parameters were estimated from published studies. Drawing parameter values from well-defined statistical distributions, one-thousand Monte Carlo simulations were conducted to estimate mean incidence and 95% uncertainty intervals. **RESULTS:** Incidence of HCC was 1.11% (0.05–4.61) with GZR/EBR compared with 23.20% (8.79–42.30) when NoTx was used and 9.83% (2.85–21.26) with peg-IFN/RBV. Compared with NoTx and peg-IFN/RBV, GZR/EBR increased QALYs by 2.38 (1.62–3.30) and 1.41 (0.76–2.22) years, respectively. COST of \$138,304 (122,047–155,296) was lowest with GZR/EBR. In comparison, Peg-IFN/RBV's COST was \$144,562 (126,553–165,999) and COST with NoTx was \$162,846 (141,624–187,487). **CONCLUSIONS:** Our model predicts that GZR/EBR will reduce the incidence of liver-related complications and disease costs and prolong QALYs in patients with HCV G1 infection and CKD.

PUK15

INVESTIGATING THE COST-EFFECTIVENESS OF BACTERIAL WHOLE-GENOME SEQUENCING FOR ENABLING TARGETED ANTIBIOTIC SELECTION IN URINARY TRACT INFECTIONS

Buchanan-Hughes AM, Griffiths A, Evans J, Slater D, Eddowes LA

Costello Medical Consulting Ltd, Cambridge, UK

OBJECTIVES: To explore the cost-effectiveness of bacterial whole-genome sequencing (bWGS) in determining antibiotic resistance and selecting antibiotics for treatment of urinary-tract infections (UTI), from the perspective of the UK National Health Service. **METHODS:** A decision-tree model was developed to compare the cost-effectiveness of UTI treatment with or without bWGS. Nitrofurantoin (NTF), trimethoprim and co-amoxiclav were designated as first-, second- and last-line treatments respectively, in accordance with treatment guidelines. Parameters extracted from peer-reviewed literature included the prevalence of resistance and disease-state utilities. Duration and cost of treatments were taken from the British National Formulary. The cost and time to perform bWGS for a complete E. coli genome using the MiSeq platform were estimated. The incremental cost-effectiveness ratio was calculated as cost (GBP) per quality-adjusted life-year (QALY). Threshold analyses were performed to explore scenarios where bWGS could become a cost-effective strategy. **RESULTS:** Using a current prevalence of resistance to NTF of 5.3% and a cost per genome of £39.69, bWGS was dominated; being more expensive and with worse health outcomes than current clinical practice. However, an ~80% reduction in cost of sequencing would lead to bWGS being cost-saving compared to current practice. Alternatively, if NTF resistance prevalence increased to 44%, bWGS could become cost-effective at £20,000/QALY. Under some scenarios, such as a reduced bWGS cost of £15 per genome and increased NTF resistance prevalence of 25%, bWGS would become a dominant strategy; being less expensive with better health outcomes than current practice. **CONCLUSIONS:** Currently bWGS is not likely to be a cost-effective option for directing the selection of antibiotics in the treatment of UTIs; however, in the probable situation that the cost of sequencing decreases and resistance to first line antibiotics increases, bWGS is expected to become a cost-effective or dominant option. This technology therefore has great potential for improving antibiotic stewardship.

PUK16

ECONOMIC EVALUATION OF MIRABEGRON VERSUS ANTIMUSCARINIC TREATMENTS IN PATIENTS WITH OVERACTIVE BLADDER FROM THE PERSPECTIVE OF THE SPANISH NATIONAL HEALTH SERVICE

Toledo A¹, Álvarez-Novoa I¹, Mora A¹, Rubio-Terrés C², Rubio-Rodríguez D², Nazir J³

¹Astellas Pharma SA, Madrid, Spain, ²Health Value, Madrid, Spain, ³Astellas Pharma EMEA, Chertsey, UK

OBJECTIVES: To assess the cost-effectiveness of mirabegron compared with antimuscarinic agents: tolterodine, solifenacin and fesoterodine, in patients with overactive bladder (OAB) symptoms from a Spanish National Health Service (NHS) perspective. **METHODS:** A Markov model was developed to simulate the course and disease management, as well as the adverse effects of treatment, in OAB patients over a period of 5 years. Direct health care costs (€, cost year 2015) included drug acquisition, primary care physician and specialist physician visits, incontinence pads, surgical procedures, adverse effects of treatment and botox injections were obtained from Spanish sources. Relative effectiveness estimates of mirabegron 50mg vs tolterodine, fesoterodine, solifenacin 5 and 10mg were obtained from a network meta-analysis, using a calibration method. Effectiveness was measured as quality-adjusted life-years (QALYs) gained. Other model inputs were derived from the literature or clinical expert opinion. Deterministic and probabilistic sensitivity analyses (SA) were undertaken. **RESULTS:** Mirabegron 50mg/day was associated with a gain of 0.01259 QALYs at an additional cost of €194 per patient vs tolterodine